

REMARKS

Any fees that may be due in connection with the filing of this paper or with this application may be charged to Deposit Account No. 06-1050. If a Petition for extension of time is needed, this paper is to be considered such Petition.

Claims 74, 75 and are pending. Claim 83 is cancelled without prejudice or disclaimer. Applicant expressly reserves the right to file divisional/continuation applications to the cancelled subject matter. Claims 74 and 75 are amended for clarity. No new matter is added.

PROVISIONAL REJECTION OF CLAIMS 74, 75, 82 AND 83 FOR OBVIOUSNESS-TYPE DOUBLE PATENTING OVER CLAIM 19 OF CO-PENDING APPLICATION SERIAL NO. 08/141,246

Claims 74, 75, 82 and 83 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 19 of co-pending U.S. application Serial No. 08/141,246 (the '246 application). The Examiner alleges that, although the conflicting claims are not identical, they are not patentably distinct from each other because claim 19 of the '246 application is drawn to a pharmaceutical composition of the compounds of the instant claims. Reconsideration of the grounds for this rejection is respectfully requested in view of the following remarks.

Relevant law

Obvious-type double patenting occurs when the difference between a first-patented invention and a later claimed invention involves only an unpatentable difference, such that grant of the second patent would extend the right of exclusivity conferred by the first patent. *See, e.g., General Foods Corp. v. Studiengesellschaft Kohle mbH*, 23 USPQ2d 1839, 1845 (Fed. Cir. 1992). Analysis for obvious-type double patenting involves a comparison of the claims at issue "with what invention is *claimed* in the earlier patent, paying careful attention to the rules of claim interpretation to determine what invention a claim *defines* and not looking to the claim for anything that happens to be mentioned in it as though it were a prior art reference." *Id.* (emphasis in original); *see, also, Ortho Pharm. Corp. v. Smith*, 22 USPQ2d 1119, 1125 (Fed. Cir. 1992) ("It is the claims, not the specification that defines an invention [citation] . . . [a]nd it is the claims that are compared when assessing double patenting."). Thus, an obviousness-type double patenting rejection is based on the claims and not on the disclosure of a patent.

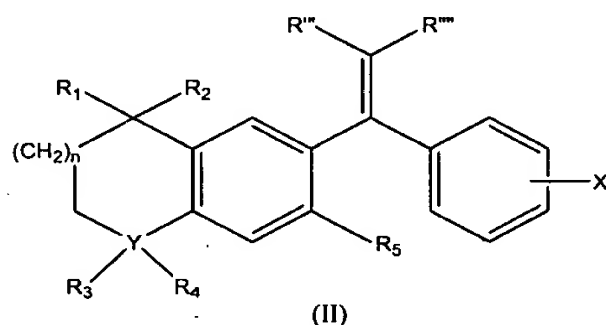
The comparison between claims in an obviousness-type double patenting inquiry requires the use of a fundamental rule of claim construction, that the invention is defined by the claim taken as a whole – every claim limitation (or each step) being material to the description

of the invention. Ortho Pharm. Corp., 22 USPQ2d at 1125. Thus, it is inappropriate to base an obviousness-type double patenting rejection on the disclosure of a patent, even when such disclosure is found in the claims. Only the claims are considered in determining whether obviousness-type double patenting exists and they are not used as disclosure but are interpreted based on the rules of claim construction.

Obviousness-type double-patenting has not been found when claims at issue do not embrace the prior patent compounds and/or the claims in the prior patent do not suggest any modification that would have produced the claimed compounds in the patent or application at issue. *See, e.g., Id.* In Ortho, obvious-type double patenting was not found in an instance in which the claims in the patent were directed to compounds that did not encompass, structurally, the compounds claimed in the prior patents, and the claims in the prior patents did not suggest a modification (based upon the principles of claims interpretation) of their compounds to produce compounds claimed in the patent at suit.

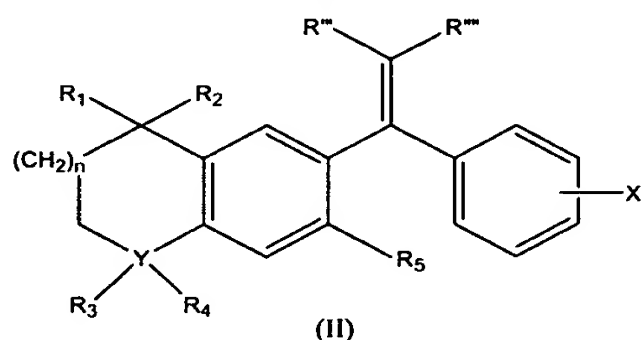
The Claims

Claim 74 is directed to a compound of formula II:



where R_1 is hydrogen or a lower alkyl having 1-4 carbon atoms; R_2 is hydrogen or a lower alkyl having 1-4 carbon atoms; Y is C; R_3 is hydrogen or a lower alkyl having 1-4 carbon atoms, and R_4 is hydrogen or a lower alkyl having 1-4 carbon atoms; R_5 is OR_7 , wherein R_7 is hydrogen or a lower alkyl having 1-6 carbon atoms; R''' is hydrogen; R'''' is hydrogen; X is $COOH$ and originates from C3, C4, or C5 of the ring; and $n = 0-1$; or a pharmaceutically acceptable ester, amide or salt thereof.

Claim 75 is directed to a compound of formula II:



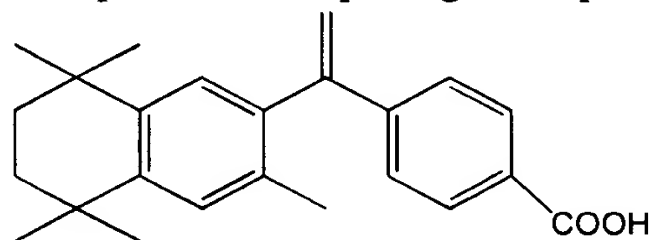
where R_1 is hydrogen or a lower alkyl having 1-4 carbon atoms; R_2 is hydrogen or a lower alkyl having 1-4 carbon atoms; Y is C; R_3 is hydrogen or a lower alkyl having 1-4 carbon

atoms, and R_4 is hydrogen or a lower alkyl having 1-4 carbon atoms; R_5 is OR_7 , wherein R_7 is hydrogen or a lower alkyl having 1-6 carbon atoms; R''' and R'''' represent hydrogen or a lower alkyl having 1-4 carbon atoms; X is $COOH$ and originates from C3, C4, or C5 of the ring; and $n = 0-1$; or a pharmaceutically acceptable ester, amide or salt thereof. Claim 82 depends from claim 74 and specifies that R_5 is OH.

U.S. application Serial No. 08/141,246 (the '246 application)

Claim 19 of the '246 application recites:

A pharmaceutical composition, comprising a compound having the formula:



and a pharmaceutically acceptable carrier.

Analysis

Claim 83 is cancelled herein. Thus, as applied to claim 83, the rejection is moot.

The compounds of the instant claims are distinct from the compound in the pharmaceutical composition of claim 19 of the '296 application. The compound in the pharmaceutical composition of claim 19 of the '296 patent has a methyl substituent at position 3 of the bicyclic system. Compounds of Formulae II of instant claims 74, 75 and 83 have a substituent R_5 at position 3 of the bicyclic system. Substituent R_5 represents OR_7 , where R_7 is hydrogen or a C_1 - C_6 alkyl. None of the pending claims in the instant application encompass a compound with a methyl substituent at position 3 of the bicyclic system. Thus, the instant compounds are distinct from the compound in the pharmaceutical composition of claim 19 of the '296 application. Further, none of the claims of the '296 application suggest a modification of the compound of its claim 19 to produce compounds as instantly claimed. Hence, it cannot be found that patent term for the compounds covered by the instant claims would extend the right of exclusivity if a patent were to be granted to the pharmaceutical composition of claim 19 of the '296 application. Therefore, as between pharmaceutical compositions including the compound recited in claim 19 in the '296 application and pending claims 74, 75 and 82, obviousness-type double patenting does not exist.

REJECTION OF CLAIMS 74, 75, 82 AND 83 UNDER 35 U.S.C. §103(a)

Claims 74, 75, 82 and 83 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Maignan *et al.* (FR2601670), which allegedly teaches a genus of compounds that

encompasses the compounds of the instant claims. The Examiner alleges that it would have been *prima facie* obvious to pick and choose the variables of the compounds of the instant claims from the genus taught in Maignan *et al.* and select the instantly claimed genus.

This rejection respectfully is traversed.

Relevant Law

For *prima facie* obviousness of a claimed invention to be established under 35 U.S.C. §103, all the claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). This principle of U.S. law regarding obviousness was not altered by the recent Supreme Court holding in KSR International Co. v. Teleflex Inc., 127 S.Ct. 1727, 82 USPQ2d 1385 (2007). In KSR, the Supreme Court stated that “Section 103 forbids issuance of a patent when ‘the differences between the subject matter sought to be patented and the prior art are such the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.’” KSR Int’l Co. v. Teleflex Inc., 127 S.Ct. 1727, 1734, 82 USPQ2d 1385, 1391 (2007).

The mere fact that prior art may be modified to produce the claimed product does not make the modification obvious unless the prior art suggests the desirability of the modification. In re Fritch, 23 U.S.P.Q.2d 1780 (Fed. Cir. 1992); see, also, In re Papesch, 315 F.2d 381, 137 U.S.P.Q. 43 (CCPA 1963). Further, that which is within the capabilities of one skilled in the art is not synonymous with that which is obvious. Ex parte Gerlach, 212 USPQ 471 (Bd. APP. 1980).

Furthermore, the Supreme Court in KSR took the opportunity to reiterate a second long-standing principle of U.S. law: that a holding of obviousness requires the fact finder (here, the Examiner), to make explicit the analysis supporting a rejection under 35 U.S.C. §103, stating that “rejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *Id.* at 1740-41, 82 USPQ2d at 1396 (citing In re Kahn, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)).

While the Supreme Court in KSR rejected a rigid application of the teaching, suggestion, or motivation (“TSM”) test in an obviousness inquiry, the Court acknowledged the importance of identifying “a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does” in an obviousness determination. KSR, 127 S. Ct. at 1731. Moreover, the Court indicated that there is “no necessary inconsistency between the idea underlying the TSM test and the Graham

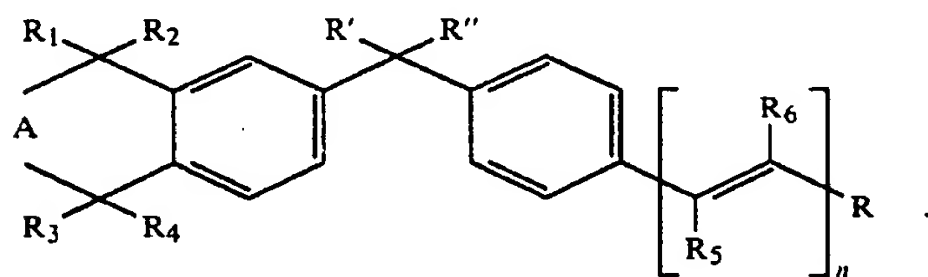
analysis.” *Id.* As long as the test is not applied as a “rigid and mandatory” formula, that test can provide “helpful insight” to an obviousness inquiry. *Id.* Thus, in cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish *prima facie* obviousness of a new claimed compound.” Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd. (No. 2006-1329 (Fed. Cir. 2007)).

The Claims

The claims are discussed above.

Teaching of Maignan *et al.* (FR2601670)

Maignan *et al.* describes bicyclic aromatic derivatives for medical, veterinary or cosmetic applications. The bicyclic derivatives include a pendent phenyl ring off of a bridging carbon, where the aromatic ring of the bicyclic system is unsubstituted, as shown below:



The substituent A is a methylene or dimethylene and substituent R is selected from among $-\text{CH}_2\text{OH}$ and $-\text{COR}_7$, where R_7 includes hydrogen and $-\text{OR}^8$, where R^8 includes hydrogen and $\text{C}_1\text{-C}_{20}$ alkyl. Maignan *et al.* describes thirty exemplary compounds on pages 6-7.

Analysis

Claim 83 is cancelled herein. Thus, as applied to claim 83, the rejection is moot.

Compounds of Formulae II of instant claims 74, 75 and 82 have a methylene group on the bridging carbon atom. None of the exemplified compounds taught in Maignan *et al.* has a methylene group on the bridging carbon atom. Further, compounds of Formulae II of instant claims 74, 75 and 82 have a substituent R_5 at position 3 of the bicyclic system. Substituent R_5 represents OR_7 , where R_7 is hydrogen or a $\text{C}_1\text{-C}_6$ alkyl. The genus and all of the compounds described in Maignan *et al.* have hydrogen at position 3 of the bicyclic system. Thus, there is no overlap between compounds of Formulae II of instant claims 74, 75 and 82 and the genus or the compounds described in Maignan *et al.* None of the exemplified compounds of Maignan *et al.* have $-\text{OH}$ or $-\text{O}(\text{C}_1\text{-C}_6 \text{ alkyl})$ as a substituent at position 3 of the bicyclic system. Maignan *et al.* does not teach or suggest replacing the hydrogen at position 3 of its bicyclic system with any substituent. Thus, one of ordinary skill in the art could not pick and

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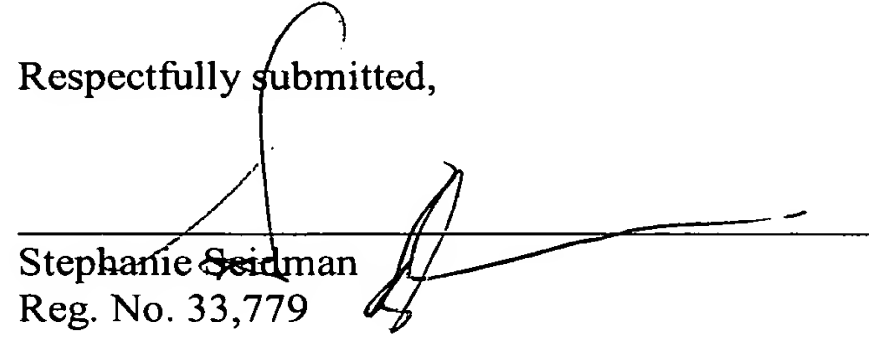
Attorney's Docket No.: 21912-002009 / 1002H
Amendment & Response

choose from among the substituents taught in Maignan *et al.* to arrive at the instantly claimed compounds. Therefore, the Examiner has failed to set forth a *prima facie* case of obviousness.

* * *

In view of the above, reconsideration and allowance of the application are respectfully requested.

Respectfully submitted,


Stephanie Seidman
Reg. No. 33,779

Attorney Docket No. 21912-002009 / 1002H

Address all correspondence to:

20985

Stephanie Seidman

Fish & Richardson P.C.

12390 El Camino Real

San Diego, California 92130

Telephone: (858) 678-5070

Facsimile: (202) 626-7796

email: seidman@fr.com